

**REMARKS**

**I. Introduction**

With the withdrawal of claims 55 to 58 herein without prejudice, with the cancellation of claims 24 to 35 and 39 to 54 herein without prejudice, and with the addition of new claims 59 to 69, claims 36 to 38 and 59 to 69 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicant notes with appreciation the acknowledgment of the claim for domestic priority.

**II. Response to Election/Restriction**

The Office Action acknowledges Applicant's election with traversal of claims 24 to 54 but makes final the restriction requirement. Applicant respectfully disagrees. However for the purposes of expediting the prosecution of this application, Applicant hereby withdraws, without prejudice, claims 55 to 58.

**III. Objection to Drawings**

In paragraphs 3, 4 and 5, the Office Action objects to the drawings. Applicants submit herewith four sheets of drawings including changes to Figures 1A, 1B, 2A, 2B, 3, 4 and 6. More specifically, Figures 1A, 1B, 2A and 2B have been separately labeled. In Figure 1B, reference signs 20 and 30 have been added. In Figure 2A, reference signs 200 and 202 have been added. In Figure 2B, reference signs 141 and 143 have been added. In Figure 3, reference sign 204 has been added. In Figure 4, reference sign 206 has been added. In Figure 6, reference signs 210.

Applicants respectfully maintain that the amendments to these Figures overcome the objections to the drawings and request that the objections be withdrawn.

**IV. Rejection of Claims 24 to 26, 31, 32, 34, 36, 38, 40 to 42, 46, 47, 49, 51 and 53 Under 35 U.S.C. § 102(b)**

Claims 24 to 26, 31, 32, 34, 36, 38, 40 to 42, 46, 47, 49, 51 and 53 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,197,848 ("Garrett et al."). Applicants note that claims 24 to 26, 31, 32, 34, 40 to 42, 46, 47, 49, 51 and 53 have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot. Furthermore, Applicants respectfully submit that claims 36 and 38 are allowable for at least the following reasons.

Claim 36 has been amended to relate to a filter module. Support for this amendment can be found at page 5, lines 27 to 28, which states that "[t]he medical item may be a filter module for dialysis, hemofiltration or ultrafiltration." Claim 36 recites that the filter module includes a closure element. Claim 36 also recites that a wall is formed in the closure element having an automatically closing slit-shaped indentation forming a germ-proof closure when closed. Claim 36 also recites a means for fastening the closure element to a connecting element disposed adjacent to the wall.

Garrett et al. purport to describe an improved closed irrigation site in a urinary irrigation device. According to Garrett et al., the site is characterized by a rigid lip defining a mouth at the distal end of an irrigation tube, a resilient, impervious membrane against the lip and covering the mouth and having a normally closed, resiliently deformable slit therethrough over the mouth, and a plug or other member securing the membrane against the lip. Garrett et al. state that the membrane may be compressed against the lip thereby biasing the slit in a closed position.

Respectfully, Garrett et al. do not anticipate amended claim 36 for at least the reason that Garrett et al. do not disclose, or even suggest, all of the limitations of amended claim 36. Specifically, Garrett et al. do not disclose, or even suggest, a filter module having a closure element, as recited in amended claim 36. In contrast, Garrett et al. purport to describe a closed irrigation site in a urinary irrigation device, and does not describe a filter module.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Garrett et al. do not disclose, or even suggest, a filter module having a closure element, as recited in amended claim 36.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

To the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." M.P.E.P. § 2112 (emphasis in original); and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Therefore, it is respectfully submitted that Garrett et al. do not anticipate amended claim 36.

As for claim 38, which depends from independent claim 36 and therefore include all of the limitations of claim 36, Applicants submit that this claim is patentable for at least the reasons submitted above in support of the patentability of claim 36.

Therefore, withdrawal of the 35 U.S.C. § 102(b) rejection, and allowance of claims 36 and 38 is respectfully requested.

**V. Rejection of Claims 35 and 50  
Under 35 U.S.C. § 102(b) or 103(a)**

Claims 35 and 50 were rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Garrett et al. Applicants note that claims 35 and 50 have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot.

**VI. Rejection of Claims 27, 33, 37, 39, 43  
48, 52 and 54 Under 35 U.S.C. § 103(a)**

Claims 27, 33, 37, 39, 43, 48, 52 and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Garrett et al. Applicants note that claims 27, 33, 39, 43, 48, 52 and 54 have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot. Furthermore, Applicants respectfully submit that claim 37 is not unpatentable for at least the following reasons.

Respectfully, Garrett et al. do not disclose, or even suggest, all of the limitations of claim 36 from which claim 37 depends. As set forth more fully above, Garrett et al. do not disclose, or even suggest, all of the limitations of claim 36 for at least the reasons that Garrett et al. does not disclose, or even suggest, a filter module having a closure element.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some

suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, nowhere do Garrett et al. disclose, or even suggest, a filter module having a closure element, as recited in amended claim 36.

Since Garrett et al. do not disclose, or even suggest, all of the limitations of claim 36 as more fully set forth above, it is respectfully submitted that Garrett et al. do not render obvious claim 37. Thus, it is respectfully submitted that claims 37 is allowable for at least the same reasons that claim 36 is allowable. In re Fine, supra (any dependent claim that depends from a non-obvious independent claim is non-obvious).

Therefore withdrawal of this rejection, and the allowance of claim 37 is respectfully requested.

**VII. Rejection of Claims 24, 26, 28, 29, 32 to 34, 36, 38, 40, 42, 44, 47 to 49, 51 and 53 Under 35 U.S.C. § 102(b)**

Claims 24, 26, 28, 29, 32 to 34, 36, 38, 40, 42, 44, 47 to 49, 51 and 53 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,929,235 ("Merry et al."). Applicants note that claims 24, 26, 28, 29, 32 to 34, 40, 42, 44, 47 to 49, 51 and 53 have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot. Furthermore, Applicants respectfully submit that claims 36 and 38 are allowable for at least the following reasons.

Merry et al. purport to describe a self-sealing percutaneous tube (e.g. catheter) introducer having a sealing mechanism to prevent blood or fluid leakage. Merry et al. state that the introducer includes spaced sealing gaskets adapted to

surround the tube, a distal sealing element being planar and having a slit. Merry et al. further state that the proximal sealing element is conical and has an annular opening at its distal and small end. Merry et al. also state that the introducer may include a side arm flushing member and/or a female luer lock connection at its proximal end.

Respectfully, Merry et al. do not anticipate amended claim 36 for at least the reason that Merry et al. do not disclose, or even suggest, all of the limitations of amended claim 36. For instance, Merry et al. do not disclose, or even suggest, a filter module having a closure element, as recited in amended claim 36. In contrast, Merry et al. purport to describe a self-sealing percutaneous tube, such as for a catheter, and does not describe a filter element. Therefore, it is respectfully submitted that Merry et al. do not anticipate claim 36.

As for claim 38, which ultimately depends on independent claim 36 and therefore includes all of the limitations of claim 36, Applicants submit that this claim is patentable for at least the reasons submitted above in support of the patentability of claim 36.

Therefore, withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claims 36 and 38 is respectfully requested.

**VIII. Rejection of Claims 35 and 50  
Under 35 U.S.C. § 102(b) or 103(a)**

Claims 35 and 50 were rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Merry et al. Applicants note that claims 35 and 50 have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot.

**IX. Rejection of Claims 27, 30, 43  
and 45 Under 35 U.S.C. § 103(a)**

Claims 27, 30, 43 and 45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Garrett et al. Applicants note that claims 27, 30, 43 and 45

have been cancelled without prejudice herein. Therefore, Applicants respectfully maintain that the rejection of these claims are moot.

**X. Conclusion**

Applicants respectfully submit that all of the pending claims of the present application are now in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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